A. The answer is: It's simple, but it's risky. Okay? I hope that answers -- I'm not trying to be evasive.

Q. Go back, at the very end of the Introduction section. You are talking about your walk-through at Actavis --

A. Right.

Q. -- this year. It says, "During this inspection, all the equipment and related questions as related to the equipment were adequately addressed with no open issues."

A. Right.

Q. What do you mean by "no open issues"?

A. Everything I asked to see, I was able to see. Any questions I had were answered. Nothing was left open.

Q. Got you.

A. I was satisfied when I walked out.

Q. All right. Let's go to Page 4, please.

At the top, underneath the formula for Digitek --

A. Right.

Q. -- you are talking about "the amount of digoxin to be used in the batch is corrected."

A. Uh-huh.

Q. Etc., etc. Do you see that paragraph?
A. Yes.
Q. Are you talking about Batch 70924 specifically there?
A. Although 7029 -- 70924 is an example, I found that in the batch records I had, this is a common practice.
Q. All right. Well, that was a bad question.
Because what I really want to ask you about is the last sentence there. It says, "The blending process did not show any procedural issues or unexpected deviations from the established directions and planned deviations as set in place."
Do you see that?
A. Yeah.
Q. In that sentence, are you referring to 70924?
A. Yes, sir.
Q. In short, it appeared appropriately blended?
A. Absolutely, based on the information I reviewed.
Q. All right. Then in the next paragraph, you are talking about the blend sampling?
A. Yes, sir.
Q. And you talk about how they're withdrawn from the blender using a sampling feed.

A. Right.
Q. And you comment on that. And that's appropriate; right?
A. Yeah.
(A discussion is held off the record.)
Q. "Three sets of samples are taken to assure material is available should a repeat blend test be required."
Is that what you wrote?
A. That's exactly what I wrote.
Q. Is it appropriate to do that?
A. As we discussed this morning, yes, Matt, it is.
Q. All right.
A. And it's also in the guidance.
Q. Let's go to the next page. The question on tabletting.
A. Yes, sir.
Q. I'd say we can skip that. We covered that before.
A. Yeah.
Q. Let's go to Page 7, please.
A. Right.
Q. Under Investigation Report, the second paragraph.

A. Right.
Q. "The investigation report goes on to note that a potential root cause for the occurrence of the thick tablets may be an artifact of the compression machine start-up procedure."
Do you see that?
A. Yes, sir.
Q. And then you say, "This is credible."
What do you mean by that?
A. That it makes perfect sense to me.
Q. Does that happen in start-up in tabletting?
A. It happens with start-up all the time, Matt; yes, sir.
Q. Is that why you discard the first start-up tablets, because they can be out of spec?
A. That's why you pull away the equipment, you put reject buckets under it to discard it, right.
Q. Now, based on the number of times that my client's press operators went through the start-up process for this particular batch, did you make any attempt to estimate the number of tablets that would be produced during the start-up process?
A. No, I didn't.
Q. And you later comment in the next paragraph that a problem could occur if these oversized tablets

made during start-up got hung up in a deduster or metal detector; right?

A. That's correct.

Q. And have you seen that happen in your own --

A. Yes.

Q. -- work in the pharmaceutical --

A. Yes, I have.

Q. -- business?

A. And my walk-through assured me that the equipment used by Actavis, the likelihood that that happens is small; very visible, very, very easy to verify.

Q. All right. All right.

We're running out of time on the tape, so as much as I don't like to do it, we need to take a break.

A. Sounds good to me.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 2:54 p.m. This is the end of Tape Number 4.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 3:09 p.m. This is the beginning of

Tape Number 5.

Q. Dr. Somma, I was asking you some questions about your report.

A. Yes, sir.

Q. So let's go to Page 8.

A. Yes, sir.

Q. Now, so far as Batch 70924A is concerned, you are aware that my client, when it finished all of its inspections on that batch, found a total of 20 double-thick tablets. Is that right?

A. That's my understanding, yes, sir.

Q. Okay. Do you have an opinion to a reasonable degree of probability as to whether or not my client, in its inspection of that batch, failed to detect any other extra-thick tablets?

A. In my experience, we never relied on a visual inspection to release a batch.

Q. Sir.

A. I didn't answer the question.

Q. You didn't.

A. No.

MR. MORIARTY: Can you read that question back, please?

Q. It was a very specific question.

(The question is read.)

MR. MILLER: Objection. Asked and answered.

A. Okay. I don't -- the probability is they did not detect all of them.

Q. Do you have an opinion to a probability as to how many were made that were extra thick that were not detected?

A. I don't have a hard and fast rule, but my rule of thumb was if you see 20, you got a thousand. That's just Russ Somma's rule. Opinion, that's all.

Q. And Russ Somma's rule, is it based on controlled trials where you tried visual inspections and tried to see how many were caught or missed?

A. It's based on my experience in scale-up of processing. It has never been confirmed by taking them out and measuring if my rule is correct.

Q. Is it based on peer-reviewed literature?

A. No.

(A discussion is held off the record.)

Q. So it's not based on actual scientific studies where you compared visual inspections' accuracy to actual defect rates?

A. No, Matt, it's not.

Q. So I want to get back to my question.

Do you have an opinion to a probability as to how many extra-thick tablets were made but not caught

during the inspection of 70924?

MR. MILLER: Objection. Asked and answered.

A. It's hard for me to say, so I would have to say the probability is high that there would be more.

Q. But you can't give me to a probability a number?

A. A number, no, sir.

Q. So 70924 is then bottled; correct? Do you have an opinion to a probability as to whether there were extra-thick tablets in every bottle?

A. That would assume a uniform distribution across the batch. I can't say yes or no; however, I think the prudent approach was to dump them back and inspect again, which they did, yes.

Q. I understand that. I'm talking about after the inspection.

A. Oh.

Q. You are saying you think there were still extra-thick tablets that my client did not detect; right?

A. That's right.

Q. And you have no actual basis for that other than your experience --

A. My experience.

Q. -- that visual inspection is not that

accurate; correct?

A. That's correct, sir.

Q. Now, my client, after the inspection, 100 percent inspection and after the tight AQL, repackaged the batch; did it not?

A. Yes. They did.

Q. Into bottles; right?

A. Yeah, uh-huh.

Q. Do you have an opinion to a reasonable degree of probability as to whether there were defective tablets in all the bottles?

A. There were certainly defective tablets there that would not be detected. Would they be in all the bottles? I don't know.

Q. Do you have any opinion to a probability as to how many of those tablets that may have been defective actually made it into the prescription of a consumer?

(A discussion is held off the record.)

A. I didn't look at the field complaints, so I don't know. You know, that would be how I should have done it. I did not do that.

(A discussion is held off the record.)

Q. Well, the field complaints, unless the consumer got it and said, "this is a double-thick

tablet," the field complaint wouldn't necessarily tell you anything?

A. Exactly.

MR. MILLER: Object to form.

A. Exactly.

Q. So it is at least conceivable that if any extra-thick tablets got out, the number of which we don't know, it may have been a return to stericycle in the process of the recall. Correct?

A. I think that's a reasonable thought, yes.

Q. Do you have any basis at all to say that extra-thick tablets were made in the batch that was made before 70924?

A. No, sir.

MS. CARTER: Object to form.

Q. Do you have any basis in any of the material you have reviewed to say that there were extra-thick tablets made in the batch after 70924?

MS. CARTER: Object to form.

A. I think the only -- my only -- my only basis would be that they did not do a thorough enough investigation on the thick batch itself. That's the only thing. Did I see anything else? No.

Q. Would you concede that it is possible that the 100 percent inspection did get all of the

extra-thick tablets out of 70924 before it went to market?

MR. MILLER: Object to form.

A. In my opinion, it could not happen.

Q. It's impossible?

A. It's impossible.

Q. Have you got any basis for that?

A. Yeah, human fatigue. That's why we have vision systems for inspection. It's a fact.

Q. Well, how many -- how many people performed the 100 percent inspection?

A. Well, customarily you don't do 100 percent inspection unless it's part of your process.

Q. Dr. Somma, there is an actual document that talks about how many people did this inspection and how many days it took them to do it.

A. Right.

Q. How many people did the 100 percent inspection?

A. I don't recall. I'd have to guess.

Q. How many -- how many days did it take them to do it?

A. I don't recall.

Q. Go to the second paragraph on Page 8.

A. Right.

Q. Is it possible that the extra-thick tablets were within the API specifications?

A. It's very probable. Or very possible. Excuse me. It's possible, yes. We don't know what they were made out of, so possible.

Q. Third paragraph.

A. Right.

Q. The second sentence.

A. Right.

Q. Can you tell me what that means?

A. "Recorded observations when considered against the theory that such a tablet would have been randomly produced during the normal manufacture of tablets is without merit."

Meaning: In my opinion that this just wouldn't happen sporadically based on what I had seen. The -- you know, simply based on observations contained in the records.

Q. So if I understand what you are then saying --

A. Right.

Q. -- after that, it lends credibility to the theory that the start-up is the more likely time when double-thick tablets were produced?

A. I think, based on the evidence that I've

looked at, yes, sir. It gets back to that.

Q. Is that the most likely cause of what happened, in hindsight?

A. It certainly is one of the things I look to go to after I do an investigation -- a review of the batch records.

Q. Have you formed an opinion to a probability aboutwhat the root cause of the double-thick tablets in 70924 was?

A. My -- my opinion is the probability is about 50 percent that that is a result of start-up and shutdown of a piece of equipment.

Q. So it's 50-50?

A. 50-50.

Q. That's actually a possibility; correct?

A. A possibility.

Q. What are the other possibilities?

A. We go on to talk about a few of them, where the tablet itself would have adhered to the punch and rode around and back in and re compressed.

Q. Yeah, but you said that was unlikely --

A. Unlikely.

Q. -- in our experience.

A. Right.

Q. So that's not probable?

A. That's unlikely.
MR. MILLER: Object. Object to form.
Q. Isn't "unlikely" not probable?
MR. MILLER: Right, but you are asking for the remaining 50 percent, so...
Q. I haven't asked anything about the remaining 50 percent. This is one question at a time here.
MR. MILLER: Well, object to form.
A. My apologies for my selection of words. I find that possible, but not probable.
Q. Okay.
A. Okay? Does that help?
Q. Yes. That's the recompression?
A. Right. The --
Q. And you -- and you said up here that "randomly producing them during normal manufacture is without merit;" correct?
A. That is correct.
Q. And would not support random compression?
A. Right.
Q. So isn't that unlikely?
A. That is -- that's unlikely.
Q. All right. Do we have any other explanations that compete with start-up for the likely explanation?
A. Nothing that I would be able to come up with

other than -- yeah, other than complete speculation.

Q. And certainly in a -- what is this, a 45-station tablet press?

A. 45 station, double sided, yes.

Q. So it's 90 tablets at start-up per revolution?

A. That's right.

Q. Per press?

A. Right, there's two presses.

Q. So even if they only had one revolution per press at start-up, you are talking about 180 tablets; right?

MR. MILLER: Object to form.

A. Yeah, I -- I'd go with that.

Q. Okay.

A. Matt, I'd even say -- even if it is twice that amount. Because remember, this thing can move around. Let's just say it's -- say it's 180 exactly. All right?

Q. Let me just stick with the number of 180 tablets --

A. Okay.

Q. -- to keep my life simple here.

A. All right.

Q. Is it likely that my client's inspection

missed 160 extra-thick tablets in that batch?

A. It's possible.

Q. I asked if it was likely.

A. Likely?

Q. Yes.

A. I think it's likely.

Q. Okay. Is it likely they missed 360?

A. Wouldn't possible -- all 360? I can't -- as the number grows, I think it becomes more apparent; but --

Q. I'm asking a specific number. Isn't it unlikely that that many people inspecting over that amount of time with a product they're familiar with would miss that many?

MS. CARTER: Objection to form.

A. As the number grows, it becomes less likely; right.

Q. Well, the number grew from 180 to 360. It's already unlikely that they missed that many; isn't that right?

A. I would have to agree that they would miss all of them? No way.

Q. Let's go to Page 11 of your report.

A. Uh-huh, got it.

Q. On the second paragraph on that page, please.

A. Okay. This means?
Q. "This means that the drug or API used for the product must be well-characterized and understood."
Do you see that?
A. Yes, sir.
Q. "We did not see any data that indicated the firm did any physio --"
A. Physicochemical.
Q. "-- physicochemical review of the drug in problem batches."
First of all, what batches are you talking about?
A. In this particular case, and I apologize that it's not clearer, by "problem batches" I meant the two -- the batches that I looked at. One was that batch that had the blend issue, and the other was the -- the double thick tablet. That was the problem batches I've talk about.
And the comment to get to is simply that I didn't see the -- customarily in my experience, the culprit is usually the API, and you do a little more looking at the API.
Q. Which blend batch are you talking about?
A. Again, this gets back to the batch I looked at.

Q. Yeah, I want to know which one it is?
A. That's 71 -- 710 -- the other one I looked at, which is 71005.
Q. 71005? Do you have Batch Record 71005 with you?
A. Yeah, I do. It's right here. And the thing I'm looking at is there is an OOS investigation tag on the back; okay?
Q. Do you know whether 71005 was released?
A. I should be able to look here; right?
Q. To market.
A. I have a finished product release form. I guess it was.
Q. Okay. That's a 0.125 batch?
A. Yeah, yes, sir. Yes it is, yeah.
Q. And what do you mean by a physicochemical?
A. Customarily what we want to look at is that API itself is behaving as it was. These things have a tendency to drift in properties: Physical appearance, morphology, things like that.
It's something Actavis would have to do to monitor the guys selling the stuff to them. Okay? It's sort of a control of your supply chain.
Q. Do you know whether they test every batch of active pharmaceutical ingredient that they receive?

A. I looked at the ANDA for Digitek, and it was clear to me that they tested all the incoming batches based on the ANDA. All incoming batches of API.

Q. Okay.

A. Right.

Q. So is that the kind of physicochemical review you are talking about?

A. No, Matt. It usually goes a little bit beyond that, and they did do that. I've seen evidence of particle size determination by a Malvern synthesizer when I did my walk through. But there's other things you look at: Thermochemistry, morphology, searching things under a microscope.

(A discussion is held off the record.)

A. This is stuff that I customarily look at when I'm doing such an investigation.

Q. Okay. I want to get back to something I was asking you before, because I forgot something. And I'm sorry if I'm repeating anything I went over this morning.

I asked you whether you had any basis to say that there were thick tablets made or released in the batches before and after 70924. Do you remember that question?

A. Yes, sir.

Q. All right. Do you have any basis to say that there were extra-thick tablets made and released to market in any other Digitek batch in 2005 or after?

A. Without having the root cause in front of us, I would say is it one-off? I can't say yes or no. So the answer is: Based on the information you presented as far as testing goes, that certainly supports there were.

My opinion is, until you have done the investigation to the level I'd expected, it's possible.

Q. Do you have any opinion to a probability what the kind of investigation you think should have been done would have revealed?

A. Yeah. Number 1, it would have identified compressability. It would have identified flowability. It would have identified any changes in morphology. And these things are all in the literature and they are in your citations -- the citations I gave you. And not only that, it's also stuff that I customarily do.

What I would be looking for is any change in crystal structure. Even at the low dose we have, it can make these things more sticky or less sticky; it can cause more flow or less flow; and things that can

happen in the background without your knowledge. Okay?

Q. But as far as I understand it, and you have certain batch records that you looked at and you have other batch records available on the plaintiffs' lawyers' website of documents; correct?

A. Uh-huh.

Q. Yes?

A. That's correct.

Q. Mark doesn't understand um-um and uh-huh.

A. Yes, yes.

Q. Okay? But you didn't see -- you don't talk about in your report problems with extra-thick tablets in any other batches before or after 70924; right?

A. That's correct.

Q. So it's conceivable that a good, solid investigation would have revealed that they just left some start-up tablets in the deduster and that it was not a common problem to other batches; right?

MR. MILLER: Object to form.

A. If I -- I would -- I would agree, had I not looked at the quality of the deduster that Actavis uses. It is not likely that that is the case.

I agree there that's a credible excuse, Matt; but after my inspection, it's not likely.

Q. Well, a good solid investigation could have found a root cause that was just a one-off; right?

A. Usually -- My point exactly. A one-off, if you agree that it's a one-off and everybody says it's okay and you move on, is fine, as long as you are absolutely certain it's a one-off.

Q. It's pretty hard to always be absolutely certain; isn't it?

A. Yes. Uh-huh.

Q. You said yes; right?

A. Yes.

Q. Have there been many times in your work in the pharmaceutical industry where you didn't come to a root cause?

A. Yes.

Q. Okay. Page 11.

A. Uh-huh.

Q. Fifth paragraph.

A. "The attributes"?

Q. Yes.

A. Uh-huh.

Q. The second sentence I don't understand.

A. Okay.

Q. "Tablet weight assures the proper level of API is contained within each tablet."

Do you see that?
A. Yes, sir.
Q. Is that true?
A. "The tablet weight assures the proper level of API is contained in each tablet."
That is true because the blend feed stock is uniform.
Q. Okay.
A. Right?
Q. I mean you could have a proper weight tablet that's 100 percent excipients; right?
A. Exactly the point, Matt. And that -- but that speaks to the blend, not the tablet.
Q. All right. And presumably that's why you do finished product testing?
A. Yes, but remember: One of the things we as an industry suffer from is end-use testing. End-use testing is not adequate in most cases to control the process.
Q. Did you ever see any place where FDA cited or warned Actavis, or even Amide, for the use of Stokes' BB2 tablet presses.
A. I don't recall seeing stuff about that.
Q. The fact that --
A. There was a question about their

qualification, but not the use as I recall it.

Q. Have you ever seen anything in the material that says that the Stokes machines weren't qualified?

A. I'd have to actually -- to be -- I vaguely remember seeing something about qualification. Whether it was the Stokes or not, Matt, I have to say I don't know. I'd have to go and look.

MR. MILLER: Well, you can take your time and look if you need to.

Q. Can you answer while you look?

MR. MILLER: No.

Q. Can you multi task?

MR. MILLER: No.

Q. Let me ask you a couple of questions before you look.

A. Yeah.

Q. FDA was well aware that my client was using Stokes BB2 tablet presses from the ANDA and every batch record; correct?

A. Absolutely. Batch presses are noted in the ANDA, yes.

Q. Even after Batch 70924, did FDA ever give a 483 or warning letter about the use of Stokes BB2 tablet presses?

A. No, I don't recall that.

And, again, my only question was whether or not they did their homework on qualifying. Okay? That's it.

Q. Is there any CFR or any other regulations requiring the use of tabletting equipment with weight controls?

A. Again, CFRs are meant to give equipment -- excuse me -- to given industry guidance, but not to mandate how they run their business. So there is no mandatory requirement that they run an instrumented tablet press.

Q. Okay. Have you ever seen any evidence that Digitek was cross contaminated with any other product?

A. Absolutely not.

Q. When there is equipment, tabletting equipment with weight controls, do they typically weigh all the tablets, or is it random sampling?

A. Well, Matt, tablets -- with a weight control system does not weigh tablets. What it weighs is the force applied to form the tablets. So what it does is it monitors the pressure in a finite environment.

To clarify, it measures every one, every tablet is measured. It's not necessarily weighed. It's indirect. Okay?

Q. Let's go to Page 13 of your report.

A. Yes, sir.

Q. It says, "The data for digoxin manufacture that we reviewed show a lack of appreciation of the dangers of this compound."

My client has made billions of digoxin tablets. How many have you been involved in making?

A. I never made digoxin, sir.

Q. So what is the basis for your statement that my client shows a lack of appreciation for the dangers of the compoundinig?

A. It seems to me that my involvement with highly potent products in the past, which is more in -- highly potent means low dose, as taken here; that more care is given to maintaining their weight, assuring homogeneity. That's all. That's what I'm trying to say.

I was comparing it to people making highly potent compounds.

Q. Well, so far as weight is concerned, did you find evidence in the material that you reviewed that there were batches which made it to market that had weight issues?

A. Not based on the run -- the run sheets I looked at, no.

Q. Okay.

A. But, again, understand that the weight of the tablet is not an indicator of its uniformity.

Q. I know. But you just used weight as an example?

A. True, but weight is in fact only an indicator of the dosage form. We get right back to the fact that the dosage form itself has to be uniform, and what I'm trying to be clear about is: You could have a uniformly weight -- a uniform weight batch, tablets right down the middle, but the blend that goes to feed that material has to be uniform, so that each aliquot is the same.

I'm sorry, if I misunderstood -- if I misunderstood.

Q. And you are basing that on the less than a handful of blend investigations that you saw in these materials. Is that right?

MR. MILLER: Object to form.

A. Here again, in my profession, usually we are brought in, we are not given all of the details. The answer (sic) is: Do we see a potential problem? And based on the information I was presented, the answer is: Yeah.

I looked for the usual candidates that lead to problems, and they were all there. Lack of

investigation, lack of understanding of the API, you know, in general.

There's a lot of investigations, Matt, and there's not a lot on the side -- you know, not a lot that focus on the things that I would have looked at.

Q. What do you mean in the next paragraph by "The firm lacks the fundamental understanding of the need to define the requirements of the product to be manufactured and take actions within their supply chain"?

A. That gets back to my API point. If, in fact, they didn't look at the API, how would they be able to feed back into their supply chain that they are getting the necessary material for the necessary functionality purpose. That's all I'm saying.

Q. Have you ever seen any FDA 483 or warning letter indicating that Actavis did not pay adequate attention to its API -- raw API?

A. I don't think that they were cited specifically on that, no.

Q. Do you have any information at all that shows that active pharmaceutical ingredient that was of inappropriate potency or purity was used in Digitek?

A. No.

Q. Does -- At Page 14 --

A. Yes.
Q. -- you are talking about V-shaped blenders and double-cone blenders --
A. Right.
Q. -- being of different geometry; right?
A. Right, uh-huh.
Q. That's a yes?
A. Yes, sir.
Q. Does FDA actually consider them part of the same family?
A. Yes, they do.
Q. What do the SUPAC guidelines say about the use of V-shaped and double-cone blenders in the same --
A. They're in the same class, but different sub classes.
Q. Does SUPAC specifically say not to use them in the same drug production?
A. It doesn't given you that guidance. When we put SUPAC together, we dealt with that question specifically to give industry flexibility, but it requires that the owner of the firm assure that that's done properly.
Q. So the bottom line is: My client's use of this blender configuration doesn't violate any --

A. Any regulation.
Q. -- regulation or guidance from SUPAC; right?
A. No, sir.
Q. Now, I've asked you a lot of questions today about whether you had evidence of out-of-spec Digitek making it to the hands of consumers. I don't need to rehash that.
But as we've gone through that, when I've been asking about out-of-spec tablets getting to consumers, what have you understood that to mean?
A. My understanding was out-of-spec tablets getting to consumers -- I've taken that simply from the analytical perspective. Okay? In other words, you have a set of specs and you test it. Right?
Q. Okay. Do the analytical specs include weight and thickness?
A. I believe those are in the testing monograph.
Q. And the testing monograph includes the range for the active pharmaceutical ingredient; right?
A. That's correct.
Q. All right. Anywhere in your report, did you say that tablets, either extra thick or outside the USP's active pharmaceutical ingredient specifications made it to the hands of consumers?
A. No, sir, I didn't make that statement.

MR. MORIARTY: Adam, how much time left do we have on the tape?

THE VIDEOGRAPHER: We have I'd say a full 40 minutes left.

MR. MORIARTY: Okay. Let's just take a --

Do you have questions that you know of right now?

MS. CARTER: One or two.

MR. MORIARTY: Let's take a five or ten-minute break. Let me go through all my notes with Ms. Downie and we will see where we are and be in a position to wrap this up. Okay?

MR. MILLER: Okay.

THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 3:48 p.m.

(A recess is taken.)

CONTINUED DIRECT EXAMINATION BY MR. MORIARTY:

THE VIDEOGRAPHER: We are back on the record. The time is 4:04 p.m.

Q. Dr. Somma, I have a couple exhibits that I hadn't asked you about yet. I'm anxious to lighten my load.

This is Exhibit 9. It's MOI145.

You know what an MOI is; don't you?

A. Yes, sir.
Q. Method operating instruction?
A. Yes, sir.
Q. Have you seen this document?
A. I have seen it, yes, sir.
Q. I didn't notice any criticisms --
A. No.
Q. -- in your report about MOI145?
A. No, sir.
Q. You don't have any criticisms of it?
A. No, sir.
Q. This is Exhibit -- it's actually Plaintiffs' Exhibit 159. Have you seen this document before?
A. Yes, sir.
Q. This is a blend failure investigation?
A. Uh-huh.
Q. Is that a yes?
A. Yes, sir.
Q. Is this one of the documents you were relying on for your opinions about the blend issues in this situation?
A. Yes, sir.
Q. And lastly, this is Exhibit 288. And I'm sorry, I can't tell you whether that's Defense or Plaintiff's Exhibit 288, but it's 288.

MR. MILLER: It's plaintiffs'.

MR. MORIARTY: Is it? Oh, it says, "Plaintiffs" on it. That's a pretty good hint.

(A discussion is held off the record.)

Q. Have you seen this document before?

A. I've seen test reports of blend assay, not this specific one.

Q. Okay. Is this an investigation of a -- either a planned or an unplanned deviation in blend uniformity? And I see in here some planned deviations, and then in the back I see an out-of-spec investigation.

Do you know what this document is?

A. I haven't looked through it yet.

Q. Did you rely on it in forming opinions in this case?

A. No, sir.

Q. All right.

A. Not that I recall.

Q. Okay. Then I won't ask you about it.

A. Okay.

Q. Does FDA have a good scientific reason to take 484 samples and test them?

MR. MILLER: Object to form.

A. That's a good question -- that's a good

question. I don't think I know the answer. From a scientific standpoint it's to confirm that you've done what they told you to do. Isn't that called -- isn't that part of vigilance, follow-up, I guess?

Q. If either Actavis' finished product testing or any testing done by Celsis Labs or any 484 sampling and testing done by FDA had been out of specification regarding Digitek, do you think that would have been important to your opinions?

A. Yes.

Q. On the flip side of that coin, isn't the absence of out-of-spec testing by all three of those entities unfinished product testing significant?

MR. MILLER: Object to form.

MS. CARTER: Object to form.

(A discussion is held off the record.)

A. I think it's significant.

Q. Did you perceive your role in this consultation to be to assess whether there were potential problems with the production of Digitek?

A. If there was a -- a problem that was not identified, perhaps; something that was not seen before.

Q. In other words, a potential problem?

A. A potential problem.

Q. And "potential" is really "possibility"; is it not?

MR. MILLER: Object to form.

A. I guess I'd have to put it in that category of possible, yeah.

Q. And the existence of a potential problem does not always mean that there is an actual problem. Is that right?

A. Unless you go about answering the question in the investigation; then you can't say if it's potential or not. But that's how I do business, how I do my job.

Q. And just to make sure I understand your thoughts on this case completely, are you saying that Actavis was, in fact, producing Digitek outside the specifications, and it's just a sheer coincidence that none of it was detected by Actavis, FDA or Celsis or pharmacists?

MR. MILLER: Object to form.

A. I would say yes.

Q. What's the scientific basis for you to say that?

A. Because without identifying as these issues myself, the potential with the blend, the observations I made with the blend, that they -- in here; the

observations with even the heavyweight tablets or whatever we call them, double-thick tablets, I am not thoroughly convinced that the investigation into the root cause uncovered all the potential issues. To my satisfaction.

Q. Are you done with your answer?

A. Yes, sir.

MR. MORIARTY: Can you read that back, please, from the "I'm not thoroughly convinced" part.

(The answer is read.)

Q. Would you agree with me that the fact that Russ Somma is not thoroughly convinced that the investigation uncovered all of the problems to your satisfaction does not mean that consumers actually received out-of-specification Digitek?

MR. MILLER: Object to form.

A. That I am not convinced, me? I am not convinced that they --

Let me have the question again, please.

I'm sorry, Matt.

(The question is read.).

A. Gee, I must be thick. I'm sorry.

Q. Okay. That's fine. If you don't understand it -- or it's late, it's late.

A. I'm a little thick. I'm sorry.

Q. You told me --
A. Yeah.
Q. -- just a minute ago that you weren't thoroughly convinced that the investigation of 70924 uncovered all the problems to your satisfaction?
A. Right.
Q. Correct?
A. That's correct.
Q. That's your opinion --
A. That's my opinion.
Q. Russell Somma?
A. Right.
Q. Correct?
A. That's right.
Q. Just because you are not thoroughly convinced that that investigation uncovered all the problems to your satisfaction does not necessarily mean that consumers actually got Digitek that was outside the specifications. Isn't that correct?
MR. MILLER: Object to form.
A. Everything I've looked at Matt, you know, for me to agree with you, I would have to be convinced that this information is there, and I'm not. I'm really not. If this was Novartis and you asked me that and you were -- you were my superior, my

recommendation is no, I'm not convinced and, therefore, I'm not comfortable with the situation. That's just the way I am.

Q. Well, are you asking me to prove to you that there weren't defective tablets in the hands of consumers?

MR. MILLER: Object to form.

A. No, I'm -- I want to see information that was done in a rigorous enough fashion that I am convinced. Sorry.

Q. All right. That's not my question.

A. I'm sorry.

Q. Okay. The purpose of this lawsuit is not for you to be convinced about the rigors of this investigation.

A. Okay.

Q. All right? I thought I'd asked this many times before today, and I don't want to rehash it and go on and on and on.

I haven't heard you say anything today where you say to a probability that you have some scientific proof that consumers got out-of-specification Digitek.

MR. MILLER: Object to form. If there's a question.

Q. Are you changing your opinion in that regard?

A. No, sir.

Q. Okay. So do you see what I'm trying to drive at here? Your level of -- your not being thoroughly convinced that the investigation revealed problems with that one batch does not prove that there was out-of-spec Digitek in the hands of consumers; does it?

MR. MILLER: Object to form.

A. And, again, what I have to point to is that all of the parts have to move and have to work properly. And there's certainly information that says in general, the quality systems here were not functioning properly.

Q. Give me all the affirmative, scientific evidence that you have that any consumers got out-of-specification Digitek in their prescription vials?

A. And, again, if all we rely upon is the specifications, we wouldn't be having this conversation. The answer is: There's got to be another dimension to it, and that dimension is the way in which they manufactured the product, and that is the point I keep trying to make.

I haven't seen anything beyond: They meet specs. If you live by the specs, you die by the

specs. It's as simple as that. That's a narrow-minded approach. And I agree with you, they all met spec.

MR. MORIARTY: I'm going to pass the witness to Ms. Downie.

CROSS EXAMINATION BY MS. DOWNIE:

Q. Dr. Somma, I have just a few questions for you.

You testified earlier today that you were contacted initially by Spyglass, Mr. Kenny's organization. Is that correct?

A. That's correct.

Q. And when were you first contacted by Mr. Kenney?

A. In March.

Q. How many times have you spoken with him regarding this litigation?

A. Two -- three times.

Q. And when he first contacted you, what did he tell you he expected your role to be in this litigation?

A. To be the technical opinion.

Q. And did he provide to you details regarding what the litigation was about?

A. Other than the fact that an oversized tablet was distributed, no. That's all I understood.

Q. Do you recall any other specifics of that conversation?

A. The conversation revolved around: Had I seen problems like this before, what is my opinion. That's about it.

Q. And had you seen problems like this before?

A. Yes, the same that I outlined before.

Q. Okay. And you said you had spoken to him about two or three times?

A. Right.

Q. Do you recall the substance of your conversations subsequently?

A. The next one was we met on Crivella to talk about the information, and then we decided -- you know, we wanted to make sure that what I focused on as far as content was something -- was nothing that he had -- that he had focused on, I guess what I'm trying to say; to understand what our approach was going to be.

Q. Why was it important that your opinions not overlap?

A. I wanted to make -- I wasn't going to produce something that was -- in other words, as I understood

it, I told you what my limitations are. I'm not a regulatory person. I'm not a compliance person. So my point was: I looked at the technical dimension. That was it.

Q. And what do you understand his role to be?

A. My understanding is, Mark is quality assurance.

Q. Quality assurance?

A. That's my understanding.

Q. Have you taken a look at his report?

A. No, sir.

No, ma'am. Sorry.

Q. That's okay. It's been a long day. I won't take offense.

Have you discussed with him what his opinions are?

A. No, ma'am.

Q. You just discussed what the scope of his opinions would be?

A. I discussed what -- where he would come down as to what his definitions and his assessment would be; not the scope.

Q. What did he tell you his definitions of --

A. Quality assurance, quality systems; you know, these kind of things that lead up to that.

Customarily when we do a technical investigation, we don't go down and drill through training manuals and SOPs. Okay?

Q. How long -- Or how many times have you worked with Mr. Kenney in investigations --

A. Never before.

Q. -- before consulting --

A. Never before.

Oh, I'm sorry. Never before.

Q. And are you -- have you been retained by Spyglass or are you retained by the plaintiffs' counsel in litigation?

A. I work for -- I work for Motley, Rice, plaintiffs' counsel.

Q. Okay. Were you given any kind of consulting fee or did you pay any consulting fee to Spyglass?

A. No, I did not.

Q. Okay.

A. This was something, when -- when we first talked, this was -- this was sorted out between myself, Motley, Rice and Spyglass. And Motley, Rice gave us the direction and we were totally separate.

Q. Other than Mr. Kenney, have you spoken to any other individuals regarding this litigation, other than of course plaintiffs' attorneys?

A. Sal Romano, who works with Mark Kenny.
Q. And how many times have you spoken -- I'm going to say Sal, because I'm not sure of the last name.
A. Right, Romano.
Two times, as far as I recall.
Q. Two times. And what were your discussions with Mr. Romano?
A. The initial investigation -- the initial interview, if I had the background in tabletting. Okay? And the second time was when we trained on how to use Crivella.
Q. Remind me again what Crivella is?
A. Crivella is a database --
Q. Right.
A. -- that all of this stuff is on. C-r-i-v-e-l-l-a.
Q. That's right. That's what you looked at the batch records on; is that correct?
A. That's where the batch records are.
Q. Why are the batch records important for you to review?
A. Batch records to me are the manner in which the company manages that part of the manufacturing. This is the hands-on approach that the operator does,

it's his direction, and that's his personal interface. That's the human interface, in my opinion. It also is a reflection of all of the sum total knowledge from development to maturation, it's in the batch records. This is how you make it.

Q. And I believe it was your testimony earlier that you believe that Actavis should have reviewed the batch records before and after?

A. That's an opinion, yes.

Q. That's right. And you have only reviewed the batch record that occurred prior. Is that correct?

(A discussion is held off the record.)

A. As close as I can get.

MR. MILLER: Asked and answered.

(A discussion is held off the record.)

Q. How many times have you personally been involved in a visual inspection of the type that was conducted by Actavis?

A. Two times.

Q. When were those?

A. I would have been -- guessing now, early '80s, and these were primarily in a clinical dosage form area. But again --

Q. What were the context of those individual

inspections, why were they being conducted?

A. In those particular cases, we were looking for capsules, if I recall. I think it was a cracked capsule.

Q. You were looking for cracked --

A. Cracked capsules.

Q. In both instances?

A. In one instance, I think. I think the other one what is I recall was a double debossed problem. It's kind of like a -- it's not a double thick, excuse me. It's sort of like an overwritten imprint. That was a total bust, by the way.

Most of my other have been systems, electronic systems.

Q. Okay.

MS. DOWNIE: I don't have any other questions. Thank you.

MR. MORIARTY: I think I just have one more.

REDIRECT EXAMINATION BY MR. MORIARTY:

Q. In that private consulting engagement you had with the extra thick tablets, was anyone asked to prove whether thick tablets were -- actually got to consumers?

A. I believe it was reacting -- I think it was

as a result of a field complaint. And, again, I didn't get deeply into that, but my understanding was a field complaint. Because there was subsequent regulatory action as I recall as a result.

Q. Is that what started the investigation?

A. I believe so.

Q. Okay. So the fact that there was a field complaint, do you know whether it was from a pharmacist or a consumer?

A. That I don't recall, Matt. I don't.

Q. All right. Well, a field complaint, was it pharmacist or consumer?

A. To be honest, Matt, I don't know. You know, because I realize that they can come in by various conduits. To be perfectly honest, I don't -- all I know is: We got a complaint.

In my business, if I got a complaint from the field. To me that means, well, somebody caught it outside the confines that you have control ove. That's bad. Okay? That's how I took it. How it came in, Matt, I can't tell you. I don't know.

Q. It's bad, but it happens?

A. It happens.

MR. MORIARTY: All right. I don't have any other questions.

MR. MILLER: I have a couple of questions.

RECROSS EXAMINATION BY MR. MILLER:

MR. MORIARTY: And, again, I object in general to you asking your own experts questions in my deposition. But go ahead.

MR. MILLER: Okay.

Q. Dr. Somma, do you have an opinion to a reasonable degree of probability that Actavis released the product Digitek outside of specification with regard to thickness specifications over the course of time that the recalled products were manufactured?

A. Yes.

Q. Do you have an opinion to a reasonable degree of probability that out-of-specification Digitek tablets were released during the time of manufacturing for the recall product that were out of specification for blend uniformity specifications?

A. Welt, that's certainly a tough one, but the answer is, again, based on what I looked at because, you know, the blend question itself in my opinion has not been resolved to an adequate level, I would have tosay yes.

Q. We went over the opinions in your expert report. Other than the information that you had

corrected --

A. Right.

Q. -- that you had picked up yesterday, has anything been shown to you or said today that alters any of the opinions that you have in your report?

A. No. We talked about the sample frequency. I was wrong there. Okay?

Q. Right. We covered that.

A. Okay. Other than the fact that I obviously made that one mistake, these are still -- these bullets are still -- are what I've put down and these are my opinions based on what I've read.

Q. Do you hold these opinions to a reasonable degree of probability?

A. Within the same probability that we have been discussing today, yeah.

MR. MILLER: I have no further questions.

MR. MORIARTY: Okay. I have more now.

RE-REDIRECT EXAMINATION BY MR. MORIARTY:

Q. Let me see if I can make sure I understand.

Mr. Miller asked you if you had an opinion to a reasonable probability about whether my client was releasing Digitek that was too thick over the course of the time of the recalled batches.

Do you remember that question he just asked you?

A. Uh-huh.

Q. How many batches?

A. How many batches were recalled?

Q. No. How many batches had extra-thick tablets that were released?

A. I'm -- that I -- the probability of giving you that number, I don't know.

Q. Which batch numbers? Which batch numbers had extra-thick tablets?

A. I think -- I'm thinking about this that this had happened and gone undetected. In that case, how would I know the batch numbers?

Q. Well, how would you know it happened and went undetected? What's that based on?

A. Simply -- simply the lack of rigor that was conducted and the way they analyzed the problem.

Q. On 70924?

MR. MILLER: Object to form.

Q. That's the batch you said had no rigor; right?

A. Yes

MR. MILLER: Object to form.

Q. Okay. That was December of 2007; correct?

A. Uh-huh, uh-huh, yes, it is.
Q. So tell me what basis you have whatsoever to say that out-of-spec tablets that were too thick ever left Actavis's premises before that even happened in 2007?
A. Well, there was the one report on the 2000 -- in 2004; right? For a thick tablet.
Q. Yeah.
A. Okay. Right?
Q. Okay. Anything else?
A. No.
Q. So out of the billions that were made, we have one tablet that actually made it to a pharmacist out of billions; correct?
A. Uh-huh.
Q. Yes?
A. That's correct, sir.
Q. And that's your basis for an opinion to a scientific probability that this was an ongoing problem?
MR. MILLER: Object to form. It misstates previous testimony.
A. Again --
Q. Yes or no?
MR. MILLER: No.

Q. Is that your basis to say that this was an ongoing problem?
A. Yes.
Q. All right. So I want to get back.
What batches and how many batches, give me the numbers, give me how many?
MR. MILLER: Objection. Asked and answered.
Q. Is the answer: You can't do it?
MR. MILLER: Objection.
MR. MORIARTY: Well, if it was answered, that was the answer I heard.
MR. MILLER: Well, you heard wrong. That's not what he said.
MR. MORIARTY: Okay.
MR. MILLER: He said he didn't know.
Q. Got any field complaints you can show me?
A. No, sir.
Q. Got any test results you can show me for thickness or weight?
A. Nothing other than what you showed me.
Q. Do you have anything scientific that you can show me besides the 2004 incident, between then and the end of November 2007, anything at all?
MR. MILLER: Objection. Asked and answered.
A. Again, everything I've looked at -- All

right? -- from a scientific basis indicates that there is a product that was released, it was within the requirements. Does that mean all of the -- there is nothing else going on?

And, again, this is simply my opinion. And in my opinion, without more investigation or better rigor than that, I can't tell you if it got out there. Is the evidence there? There is one tablet in '04 and that was it.

Q. So it is your opinion, but when I ask you for a scientific proof of the opinion, you can't point to a document in the materials you've looked at. Is that right?

MR. MILLER: Object to form.

A. There was nothing in here that clearly drew that conclusion, correct.

Q. Okay. Then the next opinion you had that Mr. Miller asked you about was essentially the same question: Did you have a reason -- an opinion to a reasonable probability that there was something about out-of-spec blend uniformity that made it to end release.

Do you remember that question?

A. Yes.

Q. Okay. Let's get -- let's get accurate about

what happens. If, in fact, there is a blend uniformity that is truly out of spec, it leads to the possibility that there will be more active pharmaceutical ingredient in some part of the batch and less in the other; correct?

A. That's correct.

Q. And a batch is not released that way; it is tabletted --

A. That's right.

Q. -- and then it goes out; correct?

So the theory would be that some tablets in that particular batch might have too much and others might have too little of the active pharmaceutical ingredient; correct?

A. That's correct.

Q. All right. Now, I don't want to plow old ground over and over, because I've asked you this before. But can you identify any field complaints where that was documented to have occurred?

MR. MILLER: Objection, asked and answered.

Q. In the material you reviewed.

A. Right. No.

Q. Can you document any test results to indicate that that actually occurred?

A. Not that I recall.

Q. Can you identify any batch by number where that occurred?

MR. MILLER: Objection. Asked and answered.

A. I think the answer was no for that.

Q. Can you identify how many batches in which that occurred?

MR. MILLER: Objection, asked and answered.

A. Again, that -- that gets into that point that I really can't make an estimate.

Q. All right. And the last question is: If that ever occurred, you can't quantify how many tablets were high or low; right?

A. Exactly. As we discussed.

MR. MILLER: Objection. Asked and answered.

A. And I apologize.

MR. MILLER: We are done.

THE VIDEOGRAPHER: Please stand by.

MR. MORIARTY: Well, stay on mark's record. You can go off the video.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 4:36 p.m. This is the end of Tape Number 5.

MR. MORIARTY: Exhibit 51A is the little white box of thumb drives. Do you have any problem with me taking this in my briefcase back to my office?

MR. MILLER: Those are three thumb drives that were produced for you.

MR. MORIARTY: Yes.

MR. MILLER: So those are yours.

MR. MORIARTY: Okay. So I don't have to leave them with the court reporter.

MR. MILLER: Right. We'd just like to have a note in the record, which is already there. So, yeah, fine.

MR. MORIARTY: I'll take them.

(The witness is excused.)

(The deposition is adjourned at 4:37 p.m.)

* * *

C E R T I F I C A T E

I, MARK SCHAFFER, a Shorthand Reporter and Notary Public of the States of New York and New Jersey, do hereby certify that prior to the commencement of the examination the witness was sworn by me to testify to the truth, the whole truth and nothing but the truth.

I do further certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I do further certify that I am neither of counsel nor attorney for any party in this action and that I am not interested in the event nor outcome of this litigation.

MARK SCHAFFER, C.S.R.

New Jersey C.S.R. License Number XI00794
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Commission No. 55985 Expiring September 13, 2011
Notary Public of the State of New York
Registration No. 01SC4953912 Expiring July 31, 2011

BOBBY R. MILLIGAN, et al.,)
)
Plaintiffs,)
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vs.)
)
ACtAVIS GROUP HF, et al.,)
)
Defendants.)
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I have read the foregoing transcript and found it to be a truthful and accurate representation of the testimony I gave in connection with the captioned matter on_____.

_____
RUSSELL SOMMA, PhD

The State of:
County of:

Sworn and subscribed before me
this day of , 2010
My commission expires:

E R R A T A S H E E T

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